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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/725,479

12/03/2003

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SIGU3013/JJC

4597

23364 7590 06/11/2008

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EXAMINER

LEWIS, KIM M

ART UNIT

PAPER NUMBER

3772

MAIL DATE

DELIVERY MODE

06/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,479	Applicant(s) SIGURJONSSON ET AL.	
	Examiner Kim M. Lewis	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-14, 16-20 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-12, 14, 16, 17, 19, 20, 25 and 27 is/are rejected.
- 7) ☒ Claim(s) 5, 13, 18 and 26 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/31/07</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> . |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 8/31/07 has been received and made of record. Note the acknowledged form PTO-1449 or substitute therefor enclosed herewith.

Response to Amendment

2. The amendment filed on 2/4/08 has been received and made of record. As requested, claims 1 and 10 have been amended, claims 6-7, 15 and 21-23 have been cancelled, and claims 24-27 are newly added.
3. Claims 1-5, 8-14, 16-20 and 24-27 are pending in the instant application.

Allowable Subject Matter

4. Claim 24 is allowed.
5. Claims 5, 13, 14, 18 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-4, 8-12, 16, 17, 19 and 20 are rejected on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 1 and 6 of U.S.

Patent No. 7,230,154 ("the '154 patent") in view of Blatchford et al. As regards claims

1-4, 8-12, 16, 17, 19 and 20, the '154 patent claims a wound dressing comprising an

absorbent core having opposed proximal and distal surface, the absorbent core

including a pattern of holes defined along the proximal surface thereof, and a discrete

skin adherent, elastomeric gel layer directly disposed along the proximal surface of the

absorbent core, said elastomeric gel layer having a plurality of through extending

apertures provided in a pattern irrespective of the pattern of holes of the absorbent core.

8. The '154 patent fails to claim a center and border portion having different

degrees of skin adherence relative to one another. Blatchford et al., however, disclose

a medical dressing with two adhesives, wherein one adhesive has greater adhesive

tack than the other so as to allow the dressing to adhere to better to the skin at certain

locations, for example, the periphery of the dressing, and adhere less to the portion which contacts the wound (abstract, col. 2, lines 12-20 and lines 31-38).

9. In view of Blatchford et al., it would have been obvious to one having ordinary skill in the art to provide the dressing of the '154 patent with multiple adhesives such as that shown in Blatchford et al. in order to allow the center portion of the dressing which contacts the wound to adhere less than, for example, the periphery of the dressing to which surrounds the wound. This will allow the dressing to firmly adhere to the skin, but only at areas surrounding the wound.

As to claims 2, 4 and 11, note the rejection of claim 1 above. In further regard to claim 2, Blatchford et al. disclose in one embodiment that the periphery of the bandage has the high tack adhesive (col. 2, lines 31-35). The high tack adhesive has greater skin adherence than the portion of the dressing located near the center (Figs. 1 and 4A). Thus, it would have been further obvious to provide the dressing of the '154 patent with a border portion having a higher tack than the center of the dressing in order to allow the periphery of the dressing greater adherence to the skin.

As regards claims 3, 9, 12 and 20, the modified device the '154 patent fails to teach a circular absorbent core and generally concentric central and border portions. However, it has been held that a change in shape of a prior device is a design consideration within the skill of the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Thus, to change the shape of the absorbent core and central and border portions would have been a design consideration to one having ordinary skill in the art.

As regards claims 8, 16, and 19, the '154 patent fails to claim that facing layer is planar along its distal and proximal surfaces. However, it would have been obvious to one having ordinary skill in the art to make the proximal and distal layers of the facing layer planar in order to better adhere to the absorbent core and the skin on which it is placed during use.

Re. claim 17, the '154 patent fails to claim that the skin adherence of each discrete section is substantially uniform. Absent a critical teaching and/or a showing of unexpected results derived from providing each discrete section of the facing with substantially uniform skin adherence, the examiner contends that as long as the border section has higher tack than the center section, the uniformity of the skin adherence or lack thereof in each discrete section is an obvious design choice, which does not patentably distinguish applicant's invention.

Claims 25 and 27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of the '154 patent in view of Blatchford et al. and Lindqvist et al.

Re. claim 25 note the double patenting rejection of claim 1 above. The '154 patent fails to teach a hydrophobic silicone based material. Lindqvist et al., however, teaches it is conventional in the art to provide wound dressing with low tack adhesives such as hydrophobic silicone gel because of its inherent low tack property.

In view of Lindqvist et al., it would have been obvious to one having ordinary skill in the art to substitute the center portion of the modified device of the '154 patent with a hydrophobic silicone based gel adhesive material because of its low tack. Applicant

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should note that it has been held that where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007) (citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, the applicants claim a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007) (citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396).

Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

With respect to claim 27, the '154 patent does not claim the facing layer is secured to the entirety of the substrate such that the peripheral edges of the facing layer and the substrate are coextensive. However, it would have been obvious to one having

ordinary skill in the art, using common sense, to secure the entirety of the facing layer to the substrate in order prevent dislodging of the substrate from the facing layer.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Wednesday to Friday, from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kim M. Lewis/
Primary Examiner
Art Unit 3772

Kml
June 9, 2008